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EXAMINER	
GOLBA, TARA M	

ART UNIT	PAPER NUMBER
3644	

DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,782	CHEN ET AL.	
	Examiner	Art Unit	
	Tara M. Golba	3644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2003 and 17 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *16 May 2003* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-93 have been considered but are moot in view of the new ground(s) of rejection.

Drawings

2. The corrected or substitute drawings were received on 5/16/03. These drawing corrections are accepted.

Claim Objections

3. Claims 19, 20, 49, 66, 91, 103, 109, and 110 are objected to because of the following informalities: In claim 19, line 4, "U/m" should be --U/ml--. In claims 20 and 66, there should be a comma after the word "animal" in the third line. In claim 49, paragraph (b), "herd member" should be --herd members--. In claim 91, line 5 of paragraph (ii), "production or lactation" should be --reproduction or lactation--. In claim 103, line 1, "A method" should be --A system--. In claims 109 and 110, line 1, "A system" should be --An apparatus--. Appropriate correction is required.

4. Claim 97 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In this case, claim 97 is identical to claim 69 and therefore does nothing to further limit claim 68.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 8 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "the means for storing a milk sample" in line 5 although claims 1-3 make no mention of a means for storing a milk sample. There is insufficient antecedent basis for this limitation in the claim.

Claim 56 recites the limitation "the means for storing a milk sample" in line 5 although claim 49 makes no mention of a means for storing a milk sample. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-3, 5, 6, 9, 14, 15, 20, 31, 33-39, 41-44, 48, 91-94, 102, and 105-111 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S. Patent Publication No. 2002/0148408 to Gompper et al.

In reference to claim 1, Gompper discloses an automated or semi-automated system for optimizing the production performance of a milk producing animal herd comprising a plurality

of herd members each assigned a unique ID code recognizable by the system (paragraph [0056]), the system comprising: means for collecting a milk sample connectable to a herd milking system (figure 1, paragraph [0054]); means for recognizing the identification codes (paragraph [0056]); means for storing data for a physiological and nutritional state of each herd member (paragraph [0076]); means for analyzing a plurality of compounds or parameters in a sample, including separate means for analyzing individual compounds or parameters and for generating a detectable signal in the presence of a compound or parameter (paragraphs [0037] and [0057]); means for directing a part of the milk sample to the separate analyzing means (figure 1, where the interconnected parts direct milk samples to analyzing means; paragraph [0037], describing a plurality of separate analyzing means that can be present in the system); the directing means controlled by data storing means such that the directing means is activated at pre-selected points in time or pre-selected time intervals in the reproduction or lactation cycles (paragraphs [0034], [0039], [0042], [0056], [0059]); and means for detecting signals, converting the signals to a set of data about physiological and nutritional condition, and outputting data (paragraphs [0070]-[0074]).

In reference to claim 2, Gompper discloses sample collecting means adapted to collect a milk sample from a mammary gland of a herd member (paragraph [0071]).

In reference to claim 3, Gompper discloses collecting milk from two or more mammary glands (paragraph [0071]).

In reference to claim 5, Gompper discloses a sample collecting means capable of collecting a subsample during a pre-selected time interval (paragraph [0071], where subsamples from different cow quarters can be collected separately).

In reference to claim 6, Gompper discloses means for storing a milk sample (paragraph [0033]).

In reference to claim 9, Gompper discloses storage means for a plurality of milk samples (paragraph [0033] describing bulk storage means).

In reference to claim 14, Gompper discloses the claimed tubing elements (figure 1).

In reference to claim 15, Gompper discloses analyzing compounds or parameters indicative of mastitis, reproduction state, and energy and nutritional state (paragraphs [0037], [0062]).

In reference to claim 20, Gompper discloses analyzing means for analyzing compounds indicating reproduction/oestrus cycles (paragraph [0055]), and these compounds are understood to include indicators of pro-oestrus, oestrus, di-oestrus, and pregnancy.

In reference to claim 31, Gompper discloses analyzing means analytically linked to a plurality of means for collecting a milk sample (figure 1, paragraph [0057]).

In reference to claim 33, Gompper discloses analyzing means spatially separated from milk collecting means (figure 1: elements 22 separated from milkers 34).

In reference to claim 34, Gompper discloses individual milk samples collected in an enclosure element (figure 1, enclosed elements of the system).

In reference to claim 35, Gompper discloses analyzing means placed at the milking site (figure 1).

In reference to claims 36 and 37, Gompper discloses a database containing individual herd member multiple data related to previous analyses of milk samples for the presence of individual compounds or parameters (paragraph [0032]). Gompper discloses the multiple data

including data for identifying the milking site, milk yield data, herd ID data, parity, reproduction, and lactation data, sample collection time data, historical physiological and nutritional data, milk composition data, feeding scheme data, and disease record data (throughout specification).

In reference to claim 38, Gompper discloses a data management system capable of comparing real time analytical data with stored data (paragraphs [0039], [0059]) and generating and transmitting an instruction message to a herd manager (paragraph [0059])

In reference to claim 39, Gompper discloses data storage means linked to a database comprising historical data descriptive of physiological and nutritional condition collected from members of one or more herds (paragraph [0039]), the database being part of the system or an external database (paragraph [0033]).

In reference to claims 41-44, Gompper discloses instruction messages about insemination (paragraphs [0055]-[0057], where estrus cycle information is provided and therefore indicates when insemination is appropriate), mastitis treatment (paragraph [0055]), and feeding scheme (paragraph [0076]), the recipient of the message being a specialist (paragraph [0076]).

In reference to claim 48, Gompper discloses the claimed method including the steps of collecting a milk sample (paragraph [0054]); contacting the sample with analyzing means to generate a signal indicating physiological or nutritional condition (paragraph [0057]); recording the character of the signal to provide a set of data, and processing the data (paragraph [0059]); and taking corrective steps to improve the physiological or nutritional condition (paragraphs [0071]-[0074]).

In reference to claims 91-94, Gompper discloses the claimed apparatus, including a milk metering device (paragraph [0055]). See discussion of claim 1 above.

In reference to claims 102, 105, and 106, Gompper discloses the claimed means for storing data for controlling the directing means. See discussion of claim 1 above.

In reference to claims 107-110, Gompper discloses directing means activated in response to detection of a change indicating an abnormality in a member of the herd (paragraphs [0056]-[0059]), the points in time or time intervals for directing milk samples scheduled subsequently to the detection (paragraph [0059], where times or time intervals are modified in response to real-time detection of parameters).

In reference to claim 111, Gompper discloses data indicating point in time in reproduction and lactation cycles (paragraph [0042]).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 10, 11, 32, and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gompper.

In reference to claim 10, Gompper discloses storage (par. [0072]) but does not disclose a plurality of storage containers. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a plurality of storage containers, since mere duplication of the essential working parts of a device involves only routine skill in the art.

In reference to claim 11, Gompper does not specifically disclose removable milk storage containers transportable to the analytical means, but it would have been obvious to make the containers removable, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

In reference to claim 32, Gompper discloses a tube element for transporting milk samples (figure 1) but does not disclose transport by conveyor elements or by hand. Nevertheless, it would have been obvious to select these modes of transport, since interchanging mechanical or automatic operations for manual operations (and vice versa) involves only routine skill in the art.

In reference to claim 103, Gompper discloses farmers and veterinarians (par. [0076], where dairy operators are understood to be farmers), and it would be obvious to include inseminators and farm management consultants in the group of specialists, because all are well-known specialists in the art, and because Gompper states that data can be used to provide information to many different specialists including equipment dealers, manufacturers, and researchers.

11. Claims 4, 7, 8, 12, 24-29, 49-60, 66, 70-74, 79-82, 84-87, 96, 98-101, and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gompper in view of U.S. Patent No. 5,743,209 to Bazin et al (cited by applicant).

In reference to claim 4, Gompper does not disclose collecting a proportional milk sample.

Bazin teaches collecting a proportional milk sample (column 3, lines 42-44) for the purpose of obtaining a sample representative of the average quality of the total milk produced during the milking of every individual animal (col. 3, lines 42-44). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include

means for collecting a proportional milk sample, as taught by Bazin, in the system disclosed by Gompper, so that the sample represents the average milk quality.

In reference to claim 7, Bazin teaches mixing means (column 8, lines 66-67) to ensure homogeneity, and it would therefore be obvious to include mixing means in the system disclosed by Gompper.

In reference to claim 8, Gompper discloses cleaning means (figure 3: wash system), connecting means for connecting sample storing means to analyzing means and the milking system (figure 1), temperature controlling means (figure 3: milk chiller), and transporting means (figure 1); and Bazin teaches means for storing a buffer or dilute solution (column 9, lines 9-12, where milk or water acts as a buffer solution).

In reference to claim 12, Gompper discloses pressure differentials throughout the system (par. [0062]), and it is understood that change in vacuum rate can create these pressure differentials between any two elements such as the milking system and the milk storage means.

In reference to claims 24-29, Gompper discloses detection of milk fat content as a compound or parameter indicative of energy balance (par. [0055]), and Bazin teaches means for analyzing protein balance by detection of urea and protein (column 4, lines 17-23). Gompper does not disclose detection of ketone body compound, but it would be within the level of ordinary skill in the art to determine the compounds that indicate energy balance, including ketone body compounds, and to test for these compounds during milk sample analysis. As Gompper notes, the system is designed to measure any components which can affect milk production and cow health (par. [0055]). Gompper and Bazin do not disclose detection of the specified ranges of MUN and BOHB, but it has been held that where the general conditions of a

claim are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art.

In reference to claim 49, Gompper discloses the claimed method except for the step of analyzing a compound indicative of the protein balance of the herd member. See discussion of claims above.

Bazin teaches the step of analyzing a compound indicative of the protein balance of the herd member (column 4, lines 17-23). The motivation for doing so is to provide milk control authorities, farmers, and researchers with information about milk quality, geographic area, and food influences (column 4, lines 6-23). Therefore, it would have been obvious to include protein analysis, as taught by Bazin, in the method disclosed by Gompper, so as to provide more information about milk quality and food influences on milk.

In reference to claims 50-60, Gompper and Bazin teach the claimed elements. See discussion of claims 2-12, respectively.

In reference to claim 66, Gompper discloses analyzing means for compounds indicative of the reproductive cycle. See claim 20.

In reference to claims 70-74, Gompper and Bazin teach the claimed invention. See discussion of claims 25-29, respectively.

In reference to claims 79-82, Gompper discloses the claimed invention. See discussion of claims 36-39, respectively.

In reference to claims 84-87, Gompper discloses the claimed instruction messages. See discussion of claims 41-44, respectively.

In reference to claims 96, 98, and 99, Gompper and Bazin teach the claimed system and method. See discussion of claims 26 and 29.

In reference to claims 100, 101, and 104, Gompper discloses reproduction and lactation data (paragraph [0042]), disease treatment data (paragraph [0072]), and the claimed specialists (see claim 103).

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gompper in view of U.S. Patent No. 5,873,323 to van den Berg et al (cited by applicant).

In reference to claim 13, Gompper discloses connection to a milk metering device and transporting tube (figure 1), and van den Berg teaches that teat cups and tubes allow milk to be collected from the desired teats (column 1, lines 50-60).

13. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gompper in view of van den Berg, U.S. Patent No. 4,385,590 to Mortensen (cited by applicant), International Patent WO 99/18774 to Postma et al. (cited by applicant), and "Automatic monitoring of the health and metabolic status of dairy cows" by Mottram (cited by applicant).

In reference to claim 16, Gompper does not teach the specific claimed compounds or parameters indicative of mastitis.

Van den Berg, Mortensen, Postma, and Mottram teach that a number of compounds and parameters are known in the art as indicators of mastitis (Van den Berg: column 4, lines 40-45; Mortensen: column 1, lines 24-29; Postma: page 1; Mottram: table 2). It would therefore be obvious to one having ordinary skill in the art to select a parameter from the group consisting of somatic cells, microbial cells, an enzyme, a protein, a lipid, a mineral, a trace element, milk temperature, conductivity, and separable particles, since these are known parameters that indicate

mastitis, and since it is desirable to detect mastitis so that animals in the herd can be treated accordingly.

In reference to claim 17, Mottram teaches analysis of an enzyme (table 2: NAGase).

In reference to claim 18, Mottram teaches analysis of the enzyme NAGase (table 2) but does not discuss LDH. Nevertheless, it would have been obvious to one having ordinary skill in the art to analyze the enzyme LDH, since it is within the level of ordinary skill in the art to determine which parameters are indicative of mastitis and should be tested for. These parameters are well-known, as discussed above in reference to claim 16.

In reference to claim 19, Mottram does not disclose detection of the claimed ranges of NAGase. However, it would have been obvious to detect amounts of NAGase in this range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

14. Claims 21-23, 45-47, and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gompper in view of Swedish Patent No. 9902972 to Bjork et al. (cited by applicant).

In reference to claims 21-23, Gompper does not disclose analysis of a hormone as indicative of reproduction cycle state. Bjork teaches detection of the hormone progesterone as an indicator of reproduction cycle state (page 4, line 26), and it would be within the level of ordinary skill in the art to discover the optimum range of progesterone being detected. Bjork teaches that the motivation for doing so is to know when insemination should take place (page 4), and it would therefore be obvious to analyze progesterone levels to determine when an animal is in heat.

In reference to claims 45-47, Gompper discloses various types of milk meters and sensors (paragraph [0055]). Bjork teaches that other known analyzing methods including biosensor analysis, biochemical assays, and radiation methods are equivalent analysis methods known in the art (page 8), thereby suggesting that different analysis methods would be equally effective in analyzing various compounds and parameters in a milk sample. It would have therefore been obvious to one having ordinary skill in the art at the time the invention was made to select an enzymatically based assay, an immunologically based assay, a biosensor analysis, a biochemical assay, a spectrometric assay, a flow injection based assay, or solid support analytical devices for analyzing a milk sample, since they are well-known analysis techniques in the art and since Bjork teaches that many different techniques would be equally effective. Gompper discloses links between analyzing means and storage and transport means for analytical devices (figure 1).

In reference to claim 95, Bjork teaches detection of the hormone progesterone as an indicator of reproduction cycle state (page 4, line 26), and it would be within the level of ordinary skill in the art to discover the optimum range of progesterone being detected.

15. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gompper in view of Bazin, van den Berg, Mortensen, Postma, Mottram, and Bjork, the combination of these references teaching detection of the claimed compounds. See discussion above.

16. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gompper in view of U.S. Patent No. 6,311,644 to Pugh (previously cited).

In reference to claim 40, Gompper does not disclose linking the external database to the system via the internet but discloses various other data links and interfaces for connecting system elements (paragraph [0038]).

Pugh teaches that internet connections and other means of outputting data such as charted displays, printouts, and communications links are equivalent devices known in the art (column 5, lines 28-39). Therefore, because internet links and other data links or output means were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute an internet connection, as taught by Pugh, for the data links disclosed by Gompper.

17. Claims 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gompper in view of Bazin as applied to claims 49 and 54, and further in view of van den Berg.

In reference to claim 61, van den Berg teaches the claimed invention. See discussion of claim 13 above.

In reference to claim 62, Gompper discloses tubing elements (figure 1) and milk flow meters.

18. Claims 63-65 and 75-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gompper in view of Bazin as applied to claim 49 above, and further in view of Mottram.

In reference to claims 63-65, Gompper, Bazin, and Mottram teach the claimed invention. See discussion of claims 17-19, respectively.

In reference to claims 75-78, Gompper discloses the claimed features. See discussion of claims 31, 32, 34, and 33, respectively.

19. Claims 67-69, 88-90, and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gompper in view of Bazin as applied to claims 49 and 66 above, and further in view of Bjork et al.

In reference to claims 67-69, Gompper, as modified in view of Bazin and Bjork, discloses the claimed invention. See discussion of claims 21-23, respectively.

In reference to claims 88-90, Bjork teaches the claimed analyzing means. See discussion of claims 45-47, respectively.

In reference to claim 97, Bjork teaches detection of the hormone progesterone as an indicator of reproduction cycle state (page 4, line 26), and it would be within the level of ordinary skill in the art to discover the optimum range of progesterone being detected.

20. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gompper in view of Bazin as applied to claim 82 above, and further in view of Pugh. See discussion of claim 40 above.

Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara M. Golba whose telephone number is (703) 305-0266. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Jordan can be reached at (703) 306-4159. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7687.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

tmg
July 17, 2003

Charles T. Jordan
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